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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
RINAUDO, JO ANN S	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/656,769	VARNUM ET AL.	
	Examiner	Art Unit	
	Jo Ann Rinaudo	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-61 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-61 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claim 46 recites SEQ ID NO: 74 and SEQ ID NO: 75 are related to human **light** chain CDR3. Claim 54 recites SEQ ID NO: 74 and SEQ ID NO: 75 are related to human **heavy** chain CDR2.

2. Claim 47 recites SEQ ID NO: 72 and SEQ ID NO: 73 are related to human **light** chain CDR2. Claim 53 recites SEQ ID NO: 72 and SEQ ID NO: 73 are related to human **heavy** chain CDR2.

3. The applicant is required to correct these errors.

Election/Restrictions

4. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 5(a)-7, 32-38, 40, and 55-59 are drawn to an antibody that binds to IL-1R1 wherein the heavy chain variable region is **SEQ ID NO: 10** and the light chain variable region is **SEQ ID NO: 12**, classified in Class 530, subclass 388.2.

II. Claims 5(b), 8,9, 32-38, 40, and 55-59 are drawn to an antibody that binds to IL-1R1 wherein the heavy chain variable region is **SEQ ID NO: 14** and the light chain variable region is **SEQ ID NO: 12**, classified in Class 530, subclass 388.2.

III. Claims 5(c), 10, 11, 32-38, 40, and 55-59 are drawn to an antibody that binds to IL-1R1 wherein the heavy chain variable region is **SEQ ID NO: 16** and the light chain variable region is **SEQ ID NO: 18**, classified in Class 530, subclass 388.2.

IV. Claims 12-14, 32-38, 40, and 55-59 are drawn to an antibody that binds to IL-1R1 wherein the heavy chain variable region is **SEQ ID NO: 20** and the light chain variable region is **SEQ ID NO: 38**, classified in Class 530, subclass 388.2.

V. Claims 12, 15, 16, 32-38, 40, and 55-59 are drawn to an antibody that binds to IL-1R1 wherein the heavy chain variable region is **SEQ ID NO: 22** and the light chain variable region is **SEQ ID NO: 38**, classified in Class 530, subclass 388.2.

VI. Claims 12, 17, 18, 32-38, 40, and 55-59 are drawn to an antibody that binds to IL-1R1 wherein the heavy chain variable region is **SEQ ID NO: 24** and the light chain variable region is **SEQ ID NO: 38**, classified in Class 530, subclass 388.2.

VII. Claims 12, 19, 20, 32-38, 40, and 55-59 are drawn to an antibody that binds to IL-1R1 wherein the heavy chain variable region is **SEQ ID NO: 26** and the light chain variable region is **SEQ ID NO: 38**, classified in Class 530, subclass 388.2.

VIII. Claims 12, 21, 22, 32-38, 40, and 55-59 are drawn to an antibody that binds to IL-1R1 wherein the heavy chain variable region is **SEQ ID NO: 28** and the light chain variable region is **SEQ ID NO: 38**, classified in Class 530, subclass 388.2.

IX. Claims 12, 23, 24, 32-38, 40, and 55-59 are drawn to an antibody that binds to IL-1R1 wherein the heavy chain variable region is **SEQ ID NO: 30** and the light chain variable region is **SEQ ID NO: 38**, classified in Class 530, subclass 388.2.

X. Claims 25-27, 32-38, 40, and 55-59 are drawn to an antibody that binds to IL-1R1 wherein the heavy chain variable region is **SEQ ID NO: 32** and the light chain variable region is **SEQ ID NO: 40**, classified in Class 530, subclass 388.2.

XI. Claims 25, 28, 29, 32-38, 40, and 55-59 are drawn to an antibody that binds to IL-1R1 wherein the heavy chain variable region is **SEQ ID NO: 34** and the light chain variable region is **SEQ ID NO: 40**, classified in Class 530, subclass 388.2.

XII. Claims 25, 31-38, 40, and 55-59 are drawn to an antibody that binds to IL-1R1 wherein the heavy chain variable region is **SEQ ID NO: 36** and the light chain variable region is **SEQ ID NO: 40**, classified in Class 530, subclass 388.2.

XIII. Claims 39 and 41 are drawn to a method of treating an IL-1 mediated disease with an antibody that binds to IL-1R1 wherein the heavy chain variable region is **SEQ ID NO: 10** and the light chain variable region is **SEQ ID NO: 12**, classified in Class 424, subclass 143.1.

XIV. Claims 39 and 41 are drawn to a method of treating an IL-1 mediated disease with an antibody that binds to IL-1R1 wherein the heavy chain variable region is **SEQ ID NO: 14** and the light chain variable region is **SEQ ID NO: 12**, classified in Class 424, subclass 143.1.

XV. Claims 39 and 41 are drawn to a method of treating an IL-1 mediated disease with an antibody that binds to IL-1R1 wherein the heavy chain variable region is **SEQ ID NO: 16** and the light chain variable region is **SEQ ID NO: 18**, classified in Class 424, subclass 143.1.

XVI. Claims 39 and 41 are drawn to a method of treating an IL-1 mediated disease with an antibody that binds to IL-1R1 wherein the heavy chain variable region is **SEQ ID NO: 20** and the light chain variable region is **SEQ ID NO: 38**, classified in Class 424, subclass 143.1.

XVII. Claims 39 and 41 are drawn to a method of treating an IL-1 mediated disease with an antibody that binds to IL-1R1 wherein the heavy chain variable region is **SEQ ID NO: 22** and the light chain variable region is **SEQ ID NO: 38**, classified in Class 424, subclass 143.1.

XVIII. Claims 39 and 41 are drawn to a method of treating an IL-1 mediated disease with an antibody that binds to IL-1R1 wherein the heavy chain variable region is **SEQ ID NO: 24** and the light chain variable region is **SEQ ID NO: 38**, classified in Class 424, subclass 143.1.

XIX. Claims 39 and 41 are drawn to a method of treating an IL-1 mediated disease with an antibody that binds to IL-1R1 wherein the heavy chain variable region is **SEQ ID NO: 26** and the light chain variable region is **SEQ ID NO: 38**, classified in Class 424, subclass 143.1.

XX. Claims 39 and 41 are drawn to a method of treating an IL-1 mediated disease with an antibody that binds to IL-1R1 wherein the heavy chain variable region is **SEQ ID NO: 28** and the light chain variable region is **SEQ ID NO: 38**, classified in Class 424, subclass 143.1.

XXI. Claims 39 and 41 are drawn to a method of treating an IL-1 mediated disease with an antibody that binds to IL-1R1 wherein the heavy chain variable region is **SEQ ID NO: 30** and the light chain variable region is **SEQ ID NO: 38**, classified in Class 424, subclass 143.1.

XXII. Claims 39 and 41 are drawn to a method of treating an IL-1 mediated disease with an antibody that binds to IL-1R1 wherein the heavy chain variable region is **SEQ ID NO: 32** and the light chain variable region is **SEQ ID NO: 40**, classified in Class 424, subclass 143.1.

XXIII. Claims 39 and 41 are drawn to a method of treating an IL-1 mediated disease with an antibody that binds to IL-1R1 wherein the heavy chain variable region is **SEQ ID NO: 34** and the light chain variable region is **SEQ ID NO: 40**, classified in Class 424, subclass 143.1.

XXIV. Claims 39 and 41 are drawn to a method of treating an IL-1 mediated disease with an antibody that binds to IL-1R1 wherein the heavy chain variable region is **SEQ ID NO: 36** and the light chain variable region is **SEQ ID NO: 40**, classified in Class 424, subclass 143.1.

XXV. Claims 60 and 61 are drawn to a method for epitope mapping using antibodies, classified in Class 435, subclass 7.1.

5. In Claims 46-54, the examiner was not able to determine which heavy chain variable regions (CDR1, CDR2, and CDR3) are associated with which light chain variable regions (CDR1, CDR2, and CDR3) recited in the claims. Applicant is required to specify which heavy variable region sequences (CDR1, CDR2, and CDR3) sequences associate with which light chain variable region sequences (CDR1, CDR2, and CDR3) in claims 46-54. If the antibodies recited in Claims 46-54 are related to one of Groups I-XII then said antibodies will be examined with one of Groups I-XII.

Linking Claims

6. Linking Claims 1, 2, 42 and 44 will be examined along with one of Groups 1-3 if one of Groups 1- 3 is elected. Claims 1, 2, 42, and 44 link inventions of Groups 1-3. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims 1, 2, 42, and 44.

7. Linking Claims 3 and 4 will be examined along with one of Groups 4-12 if one of Groups 4-12 is elected. Claims 3 and 4 link inventions of Groups 4-12. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims 3 and 4.

8. Linking Claims 43 and 45 will be examined along with one of Groups 4-9 if one of Groups 4-9 is elected. Claims 43 and 45 link inventions of Groups 4-9. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims 43 and 45.

9. Upon the allowance of the linking claims 1-4, 42-45, the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

10. Groups I-XII are separate and distinct products. The combinations of any of the heavy chain variable regions with the light chain variable region sequences encompass separate and distinct inventions. These IL-1R1 antibodies are distinct because each antibody possesses a unique structure as determined both by its heavy and light chain sequences, and by the pairing of those sequences to produce the antigen binding site.

11. Groups I-XII and Groups XIII-XXIV and XXV are related as product and method of use. The Groups can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Groups I-XII can be used for affinity purification, in addition to the methods of treating and detecting recited.

12. Groups XIII-XXIV and XXV are different methods. The methods differ with respect to one or more ingredients, method steps, and endpoints; therefore each method is patentably distinct. In the instant case, the method of treating an IL-1 mediated disease in Groups XIII-XXIV is distinct from the method for epitope mapping Group XXV. Therefore, they are patentably distinct.

13. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

14. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

15. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

16. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

17. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jo Ann Rinaudo whose telephone number is 571.272.8143. The examiner can normally be reached on M-F, 8:30AM - 5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571.272.0841. The fax phone number for the organization where this application or proceeding is assigned is 571.272.8300.

19. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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6/24/05

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